



Practitioner's Docket No. 1779-7

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____
Inventor(s)

for _____
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: GALLOWAY, Edward L.

Application No.: 10 / 612,499 Group No.: 3731

Filed: July 2, 2003 Examiner:

For: CONSTANT FORCE ACTUATOR FOR BLEEDING TIME TESTING
DEVICE

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
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(Information Disclosure Statement [6-1]—page 1 of _____)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
 - (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or
 - (3) Before the mailing date of a first Office action on the merits, whichever event occurs last."
- 37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections
and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited
and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☒ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

- ☐ Exception(s) to above:
 - ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
 - ☐ Cumulative patents or publications identified in Section 5.

Section . Concise Explanation of English Language Listed Information Items (OPTIONAL)

NOTE: *"Applicants may, if they wish, provide a concise explanation of why English-language information is being submitted and how it is understood to be relevant. Concise explanations are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more are highly relevant to patentability." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

U.S. Patent No. 5,733,300, issued on March 31, 1998 to Pambianchi et al., teaches a device that makes a standardized surgical incision one millimeter deep by five millimeters long for accurate sensitive bleeding time testing. The blade automatically retracts after incisions so as to ensure safety. The device includes a large contact surface that distributes the downward force over a wider area of skin so as to reduce the potential for deep non-standardized cuts.

U.S. Patent No. 5,662,672, issued on September 2, 1997 to Pambianchi et al., discloses a previous model of the invention covered by U.S. Patent No. 5,733,300.

U.S. Patent No. 5,031,619, issued on July 16, 1991 to Pompei, describes a method for determining bleeding time which includes a cutting assembly and a member for providing a compensation factor as a function of the temperature of the patient. The cutting assembly provides an incision of predetermined dimensions for external bleeding therethrough. The compensation member measures temperature of the patient throughout the period of external bleeding and provides a compensation factor as a function of the sensed temperature.

U.S. Patent No. 4,628,929, issued on December 16, 1986 to Intengan et al., presents another type of retractable bleeding time testing device. This device includes a housing, a hammer mechanism pivotally positioned within the housing and having a cam surface, and a self-retracting shuttle supported within the housing and including a cam follower surface. The shuttle is operative to travel in a vertical direction by the movement of the cam surface along the cam follower surface and the force exerted on the shuttle by a first spring extending from the shuttle. A cutting blade is secured to the shuttle and is operative to move out of the housing to make the

incision and then to self-retract into the housing. A second spring is operative to exert a force on the hammer to cause it to move along the cam follower surface and to cause the shuttle to travel downwardly thus causing the blade to travel out of the housing to make the incision. The second spring is also operative to move into a locked position to secure the blade within the housing after the blade has retracted back into the housing.

U.S. Patent No. 4,064,871, issued on December 27, 1977 to Reno et al., teaches a bleeding time testing device that includes a housing having a surface with a slot defining a longitudinal opening into the housing. A blade is mounted within the housing for movement of the blade tip through and along the slot. Biasing springs are provided within the housing to urge the blade through the slot a predetermined distance and along the slot for a predetermined length to control the depth and length of an incision produced with the device. A trigger is provided to initiate movement of the blade along with a safety pin to prevent the inadvertent activation of the device.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
☒ in the practitioner's file.

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SIGNATURE OF PRACTITIONER

John S. Egbert

(type or print name of practitioner)

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Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.